

REMARKS

In view of the preceding amendments and the comments which follow, amendment and reconsideration of the Official Action of May 13, 2004 is respectfully requested by Applicant.

Amendments to claims

Claim 54 has been cancelled without prejudice.

Claim 18 has been amended to limit the recitation of “organic compounds or salts thereof having a pKa value between 1.5 and 6.0” to “citric acid or a citrate salt”.

Claim 18 has been amended to replace the recitation that the solution is characterized by “having a pH between about 2.0 and 4.0” with the recitation “remaining qualitatively unchanged after storage at 2° to 8°C for 15 months” as previously recited in claim 54.

Claim 18 has been amended to change “nitrogen compounds” to “a nitrogen compound” so that it is consistent with dependent claim 22.

Claims 18, 20, 22, and 23 remain pending for examination.

Rejections under 35 USC §112, first paragraph

Claims 18, 20, 22, 23, and 54 have been rejected under 35 USC §112, first paragraph, because the specification, while being enabling for a solution comprising (a) NAD or NADP, (b) citrate/citric acid, and (c) nitrogen compounds of the claimed formula, does not reasonably provide enablement for the composition comprising any organic compound with a pKa value of 1.5-6.0. The examiner argues that the specification exemplifies a functional reagent wherein citrate is included in the composition. However, the specification fails to set forth a representative number of other organic compounds with a pKa of 1.5-6.0 that would enable one skilled in the art to make or use the composition of the invention. Since a wide array of organic compounds with a variety of functions and structures have a pKa of 1.5-6.0, it would be nearly impossible for one skilled in the art to know which organic compound would be appropriate to the invention. Moreover, the specification fails to enable one skilled in the art how to make and use the composition of the invention with any organic compound with a pKa of 1.5-6.0.

Applicant has now amended claim 18 and claims 20, 22, and 23 depending therefrom to a composition comprising citric acid or a citrate salt, thereby avoiding the rejection. The Examiner's reconsideration of this rejection as applied to claims 18, 20, 22, and 23 is respectfully requested.

Claim 20 has been rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner has pointed out that in claim 20, "the citric acid or citrate salt" lacks sufficient antecedent basis.

Applicant has now amended claim 18, from which claim 20 depends, to specifically recite "citric acid or a citrate salt", thereby avoiding the rejection. The

examiner's reconsideration of this rejection as applied to claim 20 is respectfully requested.

Rejection under 35 USC §102 (b)

Claims 18, 22, 23, and 54 have been rejected under 35 USC §102 (b) as being anticipated by Aoyama et al., U.S. Patent No. 5,424,204 (hereinafter "Aoyama 1"). The Examiner argues that Applicant claims an aqueous solution comprising NAD or NADP and derivatives thereof, one or more compounds selected from organic compounds or salts thereof with pKa of 1.5-6.0, and nitrogen compounds with a specified formula wherein pH is about 2.0 – 4.0. The nitrogen compound is a hydroxylamine derivative or salt thereof and is in the amount of 2-300 mM. Applicant alternatively claims the composition wherein it remains unchanged for 15 months at about 2°-8°C. The Examiner further argues that Aoyama 1 teaches reagent compositions comprising hydroxylamines of the claimed formula, citrate buffers, and NAD or NADP with a pH of 3-11. It is the Examiner's position that, although Aoyama 1 does not specifically disclose a composition comprising the claimed components, one in the art is able to "at once envisage" the specific combination within the generic composition, and therefore, the reference anticipates the claimed subject matter.

In rebuttal, Applicant points out that the composition of Aoyama 1, whether specifically taught or "envisioned", does not have the characteristic of Applicant's composition as recited in currently amended claim 18, i.e., Aoyama's solution does not remain qualitatively unchanged after storage for 15 months at 2°-8°C. In Table 5 (column 8), Aoyama 1 specifically teaches that none of his compositions, including the ones comprising hydroxylamine compounds (I-1, I-2, and I-3, e.g.), retained even 90% residual activity after storage at 12 months at 10° C. For this reason, Aoyama 1 does not anticipate the claimed subject matter.

In light of the present amendments and the above remarks, the Examiner's reconsideration of the rejection of claims 18, 22, and 23 under 35 USC §102 (b) is respectfully requested.

Rejection under 35 USC §103 (a)

Claims 18, 20, 22, 23, and 54 have been rejected under 35 USC §103 (a) as being unpatentable over Aoyama 1. The Examiner argues that Applicant claims an aqueous solution comprising NAD or NADP and derivatives thereof, one or more compounds selected from organic compounds or salts thereof with pKa of 1.5-6.0, and nitrogen compounds with a specified formula wherein pH is about 2.0 – 4.0. The nitrogen compound is a hydroxylamine derivative or salt thereof and is in the amount of 2-300 mM. Applicant alternatively claims the composition wherein it remains unchanged for 15 months at about 2°-8°C. The Examiner further argues that Aoyama 1 teaches reagent compositions comprising hydroxylamines of the claimed formula, citrate buffers, and NAD or NADP with a pH of 3-11. It is the Examiner's position that, although Aoyama 1 does not specifically disclose a composition comprising the claimed components, one in the art is able to "at once envisage" the specific combination within the generic composition, and therefore, the reference anticipates the claimed subject matter. The Examiner further argues that Aoyama 1 does not teach the composition comprising 5-200 mM citrate. However, it is the Examiner's position that, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize the amount of citrate buffers as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amount of citrate buffer in the composition of Aoyama 1, with a reasonable expectation for successfully obtaining the effective reagent composition of Aoyama 1.

As recited by the presently amended claims, Applicant's composition is characterized by remaining qualitatively unchanged after storage at 2° to 8°C for 15

months. In marked contrast, none of the compositions taught by Aoyama 1 retained even 90% of their activity after storage at 10°C for 12 months (Table 5). In fact, most of the compositions taught by Aoyama did not retain appreciable activity after storage for only 3 months at 10°C. Thus the claimed compositions are clearly distinguished from Aoyama 1. Moreover, based upon the stability results taught by Aoyama 1, a person skilled in the art would not be motivated by Aoyama 1 to perform further experimentation in that vein. Thus Applicant argues that not only does Aoyama 1 not teach or suggest the claimed composition, Aoyama 1 actually teaches away from the claimed composition.

Applicant respectfully requests reconsideration of the rejection as applied to claims 18, 20, 22, and 23.

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Applicant submits that his application is now in condition for allowance, and favorable reconsideration of his application in light of the present amendment and above remarks is respectfully requested. Allowance of claims 18, 20, 22, and 23 at an early date is earnestly solicited.

The Examiner is hereby authorized to charge any fees associated with this Amendment to Deposit Account No. 02-2958. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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